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**From:** Bohnenblust, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0331C49AEB404367AD226F6BD10D795D-BOHNENBLUST]  
**Sent:** 1/31/2020 5:02:22 PM  
**To:** Pierce, Amanda [pierce.amanda@epa.gov]; Striegel, Wiebke [Striegel.Wiebke@epa.gov]  
**Subject:** FW: Letter portion of 75 day letter

FYI

Eric Bohnenblust, Ph.D  
Senior Biologist  
Emerging Technologies Branch (ETB)  
Biopesticides and Pollution Prevention Division (BPPD)  
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Email: [Bohnenblust.eric@epa.gov](mailto:Bohnenblust.eric@epa.gov)

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**From:** Nathan Rose <nathan.rose@oxitec.com>  
**Sent:** Friday, January 31, 2020 11:50 AM  
**To:** Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Keith Matthews <kmatthews@wileyrein.com>  
**Cc:** Kevin Gorman <Kevin.Gorman@oxitec.com>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Reynolds, Alan <Reynolds.Alan@epa.gov>; bshurdut@gmail.com  
**Subject:** RE: Letter portion of 75 day letter

Hi Eric

Thanks for the quick response! Does the team have any availability on the 20<sup>th</sup>? We think 1.5-2 hours would be helpful if you have the availability.

We also thought it'd be helpful to give a brief outline of the responses we're intending to make for the 75-day letter.

**For the questions about MRID 506987-18:** we will answer the questions from BPPD in a new supplementary volume to 506987-18, and will be generating new experimental data to support the responses. We expect to have this response completed by 14 Feb 2020.

**For the questions and revisions to Section B (draft labels) and Section G,** we will provide a revised version of these to BPPD that adds the additional details requested by BPPD, the re-formatting to separate out Trials A and B, etc. This should enable BPPD to complete the review of these parts of the application.

Some of the requested revisions to Section G (particularly, the choice of efficacy measure, and the number and location of field studies) are likely to have cost and timing implications for the trials. They will also impact on Oxitec's desired label claims and intended use of the pesticidal product.

For these reason, we'd like to discuss these further with BPPD on 19 Feb to make sure that we're aligned regarding the data needed for an eventual Section 3 application. We don't expect these discussions to impact BPPD's ability to review Section G or reach a decision on the EUP application by 31 March 2020, as Section G is couched in broad enough terms to encompass the current recommendations from BPPD on efficacy/number of field studies, and the preferred claims that Oxitec would like to make for the pesticidal product. It should therefore be possible to continue these discussions in parallel with the review of the EUP.

Hope this helps to clarify the outline of how we plan to respond to the 75-day letter – please don't hesitate to come back with any questions.

Kind regards  
Nathan

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**From:** Bohnenblust, Eric <[Bohnenblust.Eric@epa.gov](mailto:Bohnenblust.Eric@epa.gov)>  
**Sent:** 31 January 2020 13:46  
**To:** Nathan Rose <[nathan.rose@oxitec.com](mailto:nathan.rose@oxitec.com)>; Keith Matthews <[kmatthews@wileyrein.com](mailto:kmatthews@wileyrein.com)>  
**Cc:** Kevin Gorman <[Kevin.Gorman@oxitec.com](mailto:Kevin.Gorman@oxitec.com)>; Mendelsohn, Mike <[Mendelsohn.Mike@epa.gov](mailto:Mendelsohn.Mike@epa.gov)>; Reynolds, Alan <[Reynolds.Alan@epa.gov](mailto:Reynolds.Alan@epa.gov)>  
**Subject:** RE: Letter portion of 75 day letter

Hi Keith and Nathan,

The 17<sup>th</sup> is a holiday for us and the 18<sup>th</sup> one of our team is on leave. We could meet at 8 am on Feb. 19<sup>th</sup>. Let me know if that works for you.

Thanks.

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**From:** Nathan Rose <[nathan.rose@oxitec.com](mailto:nathan.rose@oxitec.com)>  
**Sent:** Thursday, January 30, 2020 12:14 PM  
**To:** Bohnenblust, Eric <[Bohnenblust.Eric@epa.gov](mailto:Bohnenblust.Eric@epa.gov)>; Keith Matthews <[kmatthews@wileyrein.com](mailto:kmatthews@wileyrein.com)>  
**Cc:** Kevin Gorman <[Kevin.Gorman@oxitec.com](mailto:Kevin.Gorman@oxitec.com)>; Mendelsohn, Mike <[Mendelsohn.Mike@epa.gov](mailto:Mendelsohn.Mike@epa.gov)>; Reynolds, Alan <[Reynolds.Alan@epa.gov](mailto:Reynolds.Alan@epa.gov)>  
**Subject:** RE: Letter portion of 75 day letter

Hi Eric, Alan and Mike

Thanks for arranging with Keith for passing on the attachments – we have those now and are reviewing.

From a preliminary review, we're thinking that it would be most helpful to have a discussion with the relevant review team members in person on the Section G and label recommendations, including how these will relate to a future Section 3 application.

Would it be possible to do this in the week of 17-21 Feb, preferably at the start of the week, i.e. on 17 or 18 Feb?

Kind regards  
Nathan

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**From:** Bohnenblust, Eric <[Bohnenblust.Eric@epa.gov](mailto:Bohnenblust.Eric@epa.gov)>  
**Sent:** 28 January 2020 19:41  
**To:** Keith Matthews <[kmatthews@wileyrein.com](mailto:kmatthews@wileyrein.com)>  
**Cc:** Nathan Rose <[nathan.rose@oxitec.com](mailto:nathan.rose@oxitec.com)>; Kevin Gorman <[Kevin.Gorman@oxitec.com](mailto:Kevin.Gorman@oxitec.com)>; Mendelsohn, Mike <[Mendelsohn.Mike@epa.gov](mailto:Mendelsohn.Mike@epa.gov)>; Reynolds, Alan <[Reynolds.Alan@epa.gov](mailto:Reynolds.Alan@epa.gov)>  
**Subject:** Letter portion of 75 day letter

Keith and Nathan,

Attached is a copy of the 75 day letter minus the attachments. Once you have the letter and attachments tomorrow and have a chance to look through them, we can schedule a follow up call to provide clarification probably early next week sometime.

Keith just let me know what time works best for you to pick up the attachments tomorrow.

Thanks.

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Biopesticides and Pollution Prevention Division (BPPD)  
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